UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

WOMEN'S HEALTH SPECIALISTS, PLLC., Plaintiff, v. CYNOSURE, LLC, Defendant.	Case No. _____ **COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff, WOMEN'S HEALTH SPECIALISTS, PLLC ("Plaintiff" or "Plaintiff Women's Health Specialists") by its attorneys, for its Complaint against the Defendant, CYNOSURE, LLC, ("Cynosure" or "Defendant"), respectfully alleges upon information and belief as follows:

PARTIES

1. Plaintiff Women's Health Specialists, PLLC is a citizen of the State of Tennessee, it is incorporated in the State of Tennessee, and its offices are located in Germantown, Shelby County, Tennessee.

2. Defendant, Cynosure, LLC, (formerly Cynosure, Inc.) is a Delaware corporation with its headquarters in Westford, Massachusetts, and is a division of Hologic, Inc., which is a Delaware corporation that has headquarters in Marlborough, Massachusetts.

JURISDICTION AND VENUE

3. This Court has diversity jurisdiction over this case under 28 U.S.C. § 1332 because Plaintiff is a citizen of a State other than that of the citizenship of the Defendant. The

amount in controversy is alleged to be over the minimum requirement of $75,000.

4. Venue is proper in this Court because Plaintiff resides in this District.

5. This Court has personal jurisdiction over Defendant as Defendant conducts business in Tennessee and committed the acts herein in Tennessee, as described further in this Complaint.

FACTUAL BACKGROUND

6. This action concerns Plaintiff's financing and purchase of a medical device sold by Defendant called the MonaLisa Touch.

7. Plaintiff learned of the MonaLisa Touch on or about March of 2015 through direct marketing efforts by Cynosure, including emails sent by Cynosure directly to Dr. Val Vogt, a member of Women's Health Specialists practice at that time.

8. Cynosure representative, Christopher Binion ("Binion") was a representative of Defendant, and at all times discussed herein acted as Defendant's agent.

9. Binion stated that several million dollars would be spent on multimedia advertising for the MonaLisa Touch to ensure an "excellent and high profile 'branding'" for the device, and that Women's Health Specialists would be provided web and marketing support.

10. Binion also specifically promoted the MonaLisa Touch as a device to treat the symptoms of vulvovaginal atrophy. [See Christopher Binion email of March 17, 2015 attached hereto as Exhibit A and incorporated herein by reference.]

11. As a result of this promotion and representations, Plaintiff justifiably believed that the MonaLisa Touch had been approved by the United States Food and Drug Administration ("FDA") specifically for the treatment of the symptoms of vulvovaginal atrophy (VVA) as it would have been unlawful for Cynosure to market the device for these treatments unless the FDA

specifically approved such marketing.

12. At no time did Binion or any other representative for Defendant advise Plaintiff that using the MonaLisa Touch to treat symptoms of VVA was an "off-label" use.

13. Binion also represented that Plaintiff would realize well more than the lease payments from using the MonaLisa Touch.

14. Based upon Binion's representations, Plaintiff purchased the MonaLisa Touch on or about March 20, 2015, for $156,780.00.

15. The MonaLisa Touch was delivered to Plaintiff by the end March of 2015.

16. Given the considerable cost of the MonaLisa Touch, Plaintiff financed the purchase through Oneplace Capital, a finance company arranged by Defendant.

17. Plaintiff entered into an agreement with Oneplace on or about March 20, 2015, requiring Plaintiff to pay 6 monthly payments at $99 each followed by 60 monthly repayments at $3,344.51, with the last payment due in October 2020. These payments totaled $201,264.60.

18. Binion made the representations described in the paragraphs above to Dr. Val Vogt who was acting on behalf of Plaintiff in order to induce Plaintiff to finance and purchase the MonaLisa Touch.

19. On July 30, 2018, the FDA issued a warning ("July 30, 2018 FDA Warning") to "patients considering any . . . procedure or procedures intended to treat vaginal conditions and symptoms related to menopause . . ." and to "health care providers who perform vaginal procedures using energy-based devices" "to alert patients and health care providers that the use of energy-based lasers to perform . . . non-surgical vaginal procedures to treat symptoms related to menopause . . . may be associated with serious adverse events [and that] [t]he safety and effectiveness of energy-based devices for treatment of these conditions has not been established.

(Emphasis added.).

20. The FDA went on to state that "[t] o date, we have not cleared or approved for marketing any energy-based devices to treat these symptoms or conditions, or any symptoms related to menopause . . ." (emphasis added) but was "aware that certain device manufacturers may be marketing their energy-based medical devices for vaginal 'rejuvenation'" (which it defined to include the typical vaginal symptoms of menopause).

21. As succinctly explained by FDA Commissioner Dr. Scott Gottlieb, the FDA:

> recently become aware of a growing number of manufacturers marketing "vaginal rejuvenation" devices to women and claiming these procedures will treat conditions and symptoms related to menopause, urinary incontinence or sexual function. The procedures use lasers and other energy-based devices to destroy or reshape vaginal tissue. These products have serious risks and don't have adequate evidence to support their use for these purposes. We are deeply concerned women are being harmed.

Statement from FDA Commissioner Scott Gottlieb, M.D., on efforts to safeguard women's health from deceptive health claims and significant risks related to devices marketed for use in medical procedures for "vaginal rejuvenation", dated July 30, 2018, available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm615130.htm; *see also* FDA Warns Against Use of Energy-Based Devices to Perform Vaginal 'Rejuvenation' or Vaginal Cosmetic Procedures: FDA Safety Communication, dated July 30, 2018, available at https://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm615013.htm (text of warning).

22. As Commissioner Gottlieb further explained, while the FDA had cleared various laser and other energy-based devices to treat such conditions as abnormal or pre-cancerous cervical or vaginal tissue or genital warts, "the safety and effectiveness of these devices hasn't been evaluated or confirmed by the FDA for 'vaginal rejuvenation.'" *Id.* Nonetheless, companies who produce and sell these devices make "deceptive health claims" and engage in "deceptive marketing

of a dangerous procedure with no proven benefit," which he stated was, in a word, "egregious." *Id.* As the July 30, 2018 FDA Warning itself stated, using such devices for vaginal rejuvenation "may lead to serious adverse events," including vaginal burns, scarring, pain during sexual intercourse, and recurring/chronic pain.

23. Cynosure was one of the companies the FDA was referring to in its July 30, 2018 FDA Warning with regard to its marketing of its energy-based laser – the MonaLisa Touch.

24. In a letter dated July 24, 2018 to Defendant, the FDA raised a number of examples of Defendant's improper marketing of its MonaLisa Touch to treat the vaginal symptoms of menopause which the FDA could hardly have been clearer – are purposes for which it was not approved by the FDA and for which its safety and effectiveness had not been established.

25. The FDA stated that the MonaLisa Touch had only been cleared "for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology, neurosurgery, orthopedics, general and thorasic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery." July 24, 2018 Letter from Cesar A. Perez, PhD, Chief of the Surveillance and Enforcement Brach, Division of Premarket and Labeling Compliance, Office of Compliance, Center for Devices and Radiological Health to Connie Hoy, Official Correspondent, Cynosure, Inc.

26. On or about November, 2019, Plaintiff became aware of the July 30, 2018 FDA Warning, which revealed to them for the first time that the MonaLisa Touch was not FDA approved for the purposes for which Defendant sold the MonaLisa Touch to Plaintiff and the treatments for which Defendant's Sales Representative represented to Plaintiff, specifically the treatment of the symptoms of VVA.

27. Upon learning about the July 30, 2018 FDA Warning, Plaintiff ceased marketing the MonaLisa Touch as part of its practice and, given the FDA's warnings and lack of FDA approval, has only rarely used the device.

28. Had Plaintiff been aware that the MonaLisa Touch was not FDA approved for the treatments for which Defendant marketed the device to it and its providers (the treatment of the symptoms of VVA), Plaintiff would not have purchased the MonaLisa Touch or agreed to finance that purchase.

29. Plaintiff purchased the MonaLisa Touch strictly for the procedures that were marketed by Defendant as being approved by the FDA (the treatment of the symptoms of VVA), as set forth above, and for no other purpose. As a result, Plaintiff has suffered costs including the cost of purchasing and financing the purchase of the MonaLisa Touch at issue here.

FIRST CAUSE OF ACTION
FRAUD

30. Each of the preceding paragraphs are hereby incorporated by reference.

31. As set forth in paragraphs 9-13, above, Binion made material misrepresentations of then existing facts to induce Plaintiff to purchase the MonaLisa Touch and finance that purchase. Specifically, Binion promoted the MonaLisa Touch as a device to treat the symptoms of vulvovaginal atrophy meaning that the MonaLisa Touch was FDA approved for that procedure. Binion also made representations concerning the marketing and advertising that would surround the MonaLisa Touch.

32. These representations were intentionally made with the intent and purpose to cause Plaintiff to rely upon them and purchase and finance a MonaLisa Touch. Contrary to these representations, Defendant knew that the MonaLisa was not approved by the FDA to treat the symptoms of VVA at the time these representations were made or acted in reckless disregard of

this fact based on, among other things, its communications with the FDA concerning approvals of the MonaLisa Touch and its procedures.

33. Indeed, unbeknownst to Plaintiff, Defendant was seeking FDA approval of the MonaLisa Touch for VVA purposes at the time Defendant was in the process of selling the MonaLisa Touch to Plaintiff for these purposes. Specifically, on or about March 17, 2015, Defendant sought FDA approval to market its MonaLisa Touch laser for "the treatment of symptoms related to GSM including Vaginal Dryness, Vaginal Burning, Vaginal Itching, Pain, Dysuria and Dyspareunia." These facts were not made available to Plaintiff and were not available publicly.

34. Plaintiff reasonably and justifiably relied upon Defendant's representations given Defendant's superior knowledge as to what the FDA did (or did not) approve and the uses for which the MonaLisa Touch was approved by the FDA in agreeing to purchase and finance the purchase of the MonaLisa Touch.

35. As a result of the Defendant's false or misleading statements, Plaintiff suffered damages including the costs it has incurred in purchasing and financing the MonaLisa Touch. Plaintiff would not have purchased or financed the MonaLisa Touch had it not been misled by Defendant that the MonaLisa Touch was FDA approved to treat the symptoms of VVA which Defendant knew at the time was not true.

SECOND CAUSE OF ACTION
FRAUDULENT MISREPRESENTATION

36. Each of the preceding paragraphs are hereby incorporated by reference.

37. As set forth and incorporated by reference in the paragraphs above, Binion made material misrepresentations of then existing facts to induce Plaintiff to purchase the MonaLisa Touch and finance that purchase. These representations were made with the intent and purpose to

cause Plaintiff to rely upon them and purchase and finance a MonaLisa Touch.

38. The material misrepresentations were false when made.

39. In fact, contrary to these representations, Defendant knew that the MonaLisa was not approved by the FDA to treat the symptoms of VVA at the time these representations were made or acted in reckless disregard of this fact based on, among other things, its communications with the FDA concerning approvals of the MonaLisa Touch and its procedures. Indeed, unbeknownst to Plaintiff, Defendant was seeking FDA approval of the MonaLisa Touch for VVA purposes at the time Defendant was in the process of selling the MonaLisa Touch to Plaintiff for these purposes. Specifically, on or about March 17, 2015, Defendant sought FDA approval to market its MonaLisa Touch laser for "the treatment of symptoms related to GSM including Vaginal Dryness, Vaginal Burning, Vaginal Itching, Pain, Dysuria and Dyspareunia" These facts were not made available to Plaintiff and were not available publicly.

40. The facts described above were material to Plaintiff's decision to purchase the MonaLisa Touch.

41. Plaintiff reasonably and justifiably relied upon Defendant's material representations given Defendant's superior knowledge as to what the FDA did (or did not) approve and the uses for which the MonaLisa Touch was approved by the FDA in agreeing to purchase and finance the purchase of the MonaLisa Touch.

42. As a result of the Defendant's false or misleading statements, Plaintiff suffered damages including the costs it has incurred in purchasing and financing the MonaLisa Touch. Plaintiff would not have purchased or financed the MonaLisa Touch had it not been misled by Defendant that the MonaLisa Touch was FDA approved to treat the symptoms of VVA.

THIRD CAUSE OF ACTION
FRAUD IN THE INDUCEMENT

43. Each of the preceding paragraphs are hereby incorporated by reference.

44. As set forth in the paragraphs above, Binion made material false statements of then existing facts to induce Plaintiff to purchase the MonaLisa Touch and finance that purchase.

45. Binion made such statements with knowledge of their falsity or with utter disregard for their truth since at the same time Defendant was seeking FDA approval for VVA purposes.

46. These representations were made with the intent of inducing reliance by Plaintiff upon the statements such that Plaintiff would purchase and finance a MonaLisa Touch.

47. Plaintiff reasonably and justifiably relied upon Defendant's representations given Defendant's superior knowledge as to what the FDA did (or did not) approve and the uses for which the MonaLisa Touch was approved by the FDA in agreeing to purchase and finance the purchase of the MonaLisa Touch.

48. As a result of the Defendant's false or misleading statements and Plaintiff's reliance on them, Plaintiff suffered damages including the costs it incurred in purchasing and financing the MonaLisa Touch.

FOURTH CAUSE OF ACTION
UNJUST ENRICHMENT

49. Each of the preceding paragraphs are hereby incorporated by reference.

50. Defendant has received the purchase price it charged Plaintiff to purchase the MonaLisa Touch from Oneplace Capital, the financing company Defendant recommended to Plaintiff.

51. Plaintiff would not have incurred any of the costs of both the MonaLisa Touch and the financing charges had Defendant been truthful about the absence of FDA approval to treat the

symptoms of VVA.

52. Plaintiff's purchase of the MonaLisa Touch conferred a benefit on Defendant.

53. By virtue of its obtaining these monies paid by Plaintiff to purchase and service the MonaLisa Touch, Defendant has appreciated that benefit, knowingly accepted that benefit, and has been unjustly enriched to the detriment of Plaintiff.

54. Defendant's retention of the monies it has gained through its wrongful acts and practices would be unjust considering the circumstances of its obtaining those monies.

55. It would be against equity and good conscience for Defendant to retain these funds given the misrepresentations Defendant utilized to induce Plaintiff to purchase and finance the MonaLisa Touch.

56. Plaintiff was damaged and is entitled to full reimbursement of the unlawfully obtained payments and finance charges.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully asks the Court to enter judgment against Defendant for all of the following:

A. For compensatory, equitable and/or restitutionary damages available under the causes of action set forth herein according to proof; and

B. For such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff demands a trial by jury on all questions of fact raised by the Complaint.

Dated: January 6, 2021

Respectfully Submitted,

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*Pro Hac to be Filed